

EXHIBIT L



**The Comments of the
Biotechnology Industry Organization
on the
United States Patent & Trademark Office
Proposed Rule Changes Concerning
Claims Containing Alternative Language
October 9, 2007**

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By Electronic Mail and Courier

By Electronic Mail to markush.comments@uspto.gov

Mail Stop comments- Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA, 22313-1450

Attention: Kathleen Fonda

Comments to Notice of Proposed Rulemaking Entitled: *Examination of Patent Applications That Include Claims Containing Alternative Language*

Dear Ms. Fonda:

The Biotechnology Industry Organization (BIO) appreciates the opportunity to provide comments on the United States Patent and Trademark's (PTO): *Examination of Patent Applications That Include Claims Containing Alternative Language*, 72 FR 154 (August 10, 2007). BIO is an industry organization with a membership of more than 1,100 biotechnology companies, academic institutions, state biotechnology centers and related organizations in all 50 states. BIO members are involved in the research and development of health care, agricultural, industrial, and environmental biotechnology products. The United States leads the world in biotechnology research and development. The biotechnology industry, fueled by the strength of the U.S. patent system, has provided jobs for well over 200,000 people in the United States, generated hundreds of drug products, medical diagnostic tests, biotech crops, and environmental products. In the healthcare sector alone, the industry has developed and commercialized over 300 biotechnology drugs and diagnostics; and there are over 370 products in the pipeline. In the agricultural field, biotechnology innovations are growing the economy worldwide by simultaneously increasing food supplies, reducing pesticide damage to the environment, conserving natural resources of land water and nutrients and increasing farm income. Biotechnology innovation has the potential to provide treatments for some of the world's most intractable diseases and address some of the most pressing challenges facing our society today.

The United States patent system is designed to spur innovation and encourage research and development of new products for the benefit of society. Particularly in the biotechnology sector, innovation protected by strong, predictable patents catalyzes investments and growth. Jobs are created and society benefits from both the availability of new products, services or treatments and the economic opportunities surrounding these new discoveries. The ability of applicants to obtain protection for the entirety of their invention, that is, the genus, rather than only the individual species, is critical to the

development of these innovations. Many life-saving products are but a species among many in a genus claim obtained in a patent. The ability to further pursue the individual species and submit them to the additional regulatory reviews and analysis required for such products is predicated on the ability to obtain comprehensive genus patents which cover more than a single disclosed embodiment.

The rules proposed by the PTO would adversely impact innovation, especially in the biotechnology sector, by reducing the ability of applicants to obtain coverage for the full scope of their invention. Products falling within the scope of such inventions frequently take many years to complete and come to the marketplace, for example, due to the lengthy process of drug discovery and development, testing and FDA approval. The resultant reduction in the coverage of the patent has the attendant result of decreased interest in financial backing for the initial research and product development.

The PTO reports that this proposed rule is part of the effort to increase the quality of patents and decrease the backlog of pending patent applications. However, allowing Examiners to restrict within a single claim will not decrease the number of applications being filed by an applicant. Rather, it will increase the number of applications necessary to cover various aspects of the invention, and add to the growing backlog of unexamined applications at the PTO. Moreover, and exceedingly important, this restriction within a single claim will prevent an Applicant from obtaining the full coverage of the invention because many species do not equate to the genus represented in many biotech inventions. This would deprive the Applicants of the coverage to which they are entitled and result in the loss of valuable intellectual property (IP) to the company and harm to the public waiting for biotechnology developments to improve their lives.

Patents and Biotechnology

The biotechnology industry, perhaps more than any other, is dependent upon the protection of patents. This protection is a crucial first step since often a biotechnology company must expend hundreds of millions of dollars on research and development of the product before these investments produce any monetary recovery. Without this patent protection, the investment of time and money into developing biotechnological advances would decrease markedly.

The proposed rules would reduce the ability of a biotechnology Applicant to obtain the coverage of the comprehensive genus as invented and described in the patent application. Piece-meal protection of these valuable contributions would detract from their desirability to investors. A narrow patent obtained before clinical trials and which provides protection of a small group of species creates uncertainty since the ultimate most valuable product resulting from years of regulatory testing and clinical trials may or may not be encompassed by the claims. In such a situation, an investor may be reluctant to make the incredible investment necessary to develop the IP.

The cost of IP development in the biotechnology sector stems from the substantial time and money required to bring a product through the discovery phase, through the lead

optimization phase, and into the product development phase. In addition, for healthcare products, preclinical testing followed by clinical trials is required to obtain the necessary regulatory approval for acceptance and marketing. Clinical testing cannot occur until lead compounds have been weeded from the large genus of invented compounds during the development process. Similarly, commercialization of a transgenic crop requires regulatory approval after multiple years of field trials to demonstrate not only efficacy but environmental and nutritional safety after preceding years of trials have established and confirmed the advantages of certain species within a genus invention. The scope of patent protection must be inclusive enough to encompass several lead compounds, and variations thereof, in order to attract the necessary investments of time, money and scientific resources.

The ability to protect these critical inventions with inclusive genus language is essential to the biotechnology industry. The proposal by the PTO to permit a restriction within a claim and thus eliminate the right of the Applicant to present the claim in his or her most beneficial format will have a dramatic adverse effect on our members.

Genus Claims and Biotechnology

Cutting-edge developments frequently claim a genus invention that protects a class of products. The inventors are entitled to this more general scope since they are the first inventors and there is in many cases no prior art to preclude patentability. These inventions arise out of companies, or universities, from which start-up companies license the inventions. On the basis of these patents, the companies attract financing that fuels the development cycle, and in many cases, these fledgling companies are later acquired by larger companies with more capability to develop the promising products. This business model is fundamentally American and has been a key aspect of the economic growth of our industry over the last two decades. Without coverage of the comprehensive invention, the IP is less attractive and fewer of these licenses, financings and deals are likely to occur. Consequently, less research and development (R&D) will be funded with potential adverse impacts to our healthcare and other biotechnology sectors. This in turn jeopardizes the U.S.'s global position as the leader in the field of biotechnology.

In its proposed rule, the PTO asserts that applications are becoming more complex and claims more extensive, with many species being claimed in the Markush format as alternatives. While BIO is sympathetic to these concerns, the significant changes authorized by the proposed rule would eliminate rights of the Applicant to completely claim his or her invention. Patent certainty, predictability, quality and appropriate scope are critical to BIO's members and for this reason, BIO is grateful for the opportunity to work with the PTO to improve the processes and procedures for all parties involved.

To this end, we call attention to a number of specific concerns about the proposed rule that in conjunction with rules that are currently being implemented (e.g. the PTO's rules on continuations and claims) would significantly impact patent scope, strength and predictability for biotechnology applicants.

BIO's Concerns with the PTO's Proposed Rule

The Proposed Changes to the Rules will Increase Costs and Uncertainty and are Unnecessary

Biotechnology applicants are compelled by the unique nature of biotechnology inventions to use alternatives in claims. While it is true that in some situations, biotechnology inventions may be claimed by true genus claims, very often the only alternative to adequately capture the full scope of the claim is through the Markush format. There may be no acceptable broad inclusive phrase that can be utilized to define the group at issue, particularly when it is the Applicant who discovered the group and its inventive functions or effects in a particular system. This is exactly the situation which spawned Markush practice, which has been in existence for over a hundred years. We are concerned that this proposed rule disproportionately impacts the very industries for which this practice was originally invented.

In addition, BIO is concerned that the proposed rules appear to arbitrarily distinguish one set of applications for closer scrutiny than others based solely on the Applicant's choice of language. We believe that such rules are unnecessary as Examiners may already object to claims that are unclear, i.e., those claims which do not "particularly point[] out and distinctly claim[] the subject matter the applicant regards as his invention".¹

By allowing Examiners to restrict within a single claim, the proposed rule exacerbates existing problems associated with restriction practice. While Applicants are given the option of trying to convince the Examiner that the genus represents a single invention, our experience has been that these attempts have been met with little success. Consequently, Applicants will be faced with significant additional expenditures for the filing of additional applications, for prosecution, and for the maintenance fees for any resultant patents. This piecemeal restriction and subsequent examination would strain budgets and would necessitate an applicant to role the dice on which species to pursue. The unfortunate unintended consequence of this would be that companies will discard valuable species along the way making development of potentially useful products less likely. These losses of exclusive rights are potential public losses in the development of innovative products for healthcare, advanced nutrition and the environment.

The inability to obtain a genus claim covering alternatives will also lead to patent uncertainty. In most, if not all cases, the commercial end product of biotechnology R&D is not entirely clear at the beginning of the analysis or patenting process. Limited patent scope reduces the value of the patent, thus greatly reducing the attractiveness of the patent portfolio protecting a biotech product. This in turn greatly hinders the ability of the biotechnology entrepreneur to generate investment into the development of said product.

¹ 37 U.S.C. § 112, second paragraph.

The proposed rules also create uncertainty for biotechnology patent applicants. In allowing genus claims to be carved into smaller species or subgenera, the risk exists that the subgenus not adequately disclosed in such a manner to provide an adequate written description. This unfortunately, may expose the patents to later vulnerability should a legal challenge arise.

Adding to this, is the ambiguous language "difficult to construe"² in the proposed rule, which may be arbitrarily and capriciously applied by the examiner. Claims using Markush language, admittedly, can be lengthy and complex. Claims that are "difficult to construe" based on poor structure, poor grammar, atypical word usage and multiple other factors, however, are certainly not limited to Markush claims. In other words, claims that are difficult to construe come in many linguistic formats. However, the proposed rules create an arbitrary dichotomy between Applicants who choose or are forced to use Markush format (e.g., inability to define an invention other than in Markush format) and Applicants who do not use Markush format.

We are also concerned that the proposed rule will create additional work for the examiner and contribute to a decrease in patent quality. As these rules are implemented and rejections are made, appeals undoubtedly will follow forcing Examiners to respond to these appeals and further restricting their ability to adequately examine pending applications. As Examiners focus more energy on appeals, the quality of examination, and therefore that of issued patents, will also decline.

The Proposed Rule Would Restrict or Eliminate Applicant's Ability to Claim the Invention as He or She Chooses

35 U.S.C. §112 second paragraph requires that the specification shall conclude with one or more claims that the Applicant regards as his or her invention. Permitting the restriction within a single claim removes that ability from the Applicant. The proposed rule allows the Examiner to dictate what the claims will cover without an examination and, in many cases, will eliminate the Applicant's right to broad protection of his invention.

The proposed rule also mandates that no alternative may itself be defined as a set of further alternatives and prohibits any alternative from being included within the scope of another alternative. Such arbitrary limitations again adversely affect the right of an Applicant to select the manner of the claim. The use of these formats is sometimes the most expeditious ways of describing the invention. We do not believe that such a format renders a claim any less clear or necessarily any more difficult to search. Instead, this proposal only serves to limit the ability of a biotech applicant to claim an invention as he/she deems necessary.

In a situation where the Examiner finds an elected species to be allowable but deems the claims not enabled or lacking an adequate written description over their entire scope, another provision of the proposed rule would permit the Examiner to require restriction

² Proposed rule 37 C.F.R. §1.175(j)(1).

of the claims to the elected species. This provision is likely to be applied most extensively against biotechnology Applicants given the frequency of enablement and written description rejections in this area. The provision could therefore, conceivably prevent an Applicant from actually advancing the application to the Board of Patent Appeals and Interferences for the consideration of these rejections. Furthermore, it is not clear what options the Applicant would have at this point because restrictions are petitionable, not appealable. This, in conjunction with the impact of the rules on continuing applications would preclude Applicant from filing the restricted subject matter as a divisional application because the subject matter would already have been examined. This is an untenable consequence and would seemingly require Applicant to utilize one of his or her precious continuations in order to further pursue this subject matter.

BIO also notes that 37 CFR 1.142(c) does not appear in the version of the rule reproduced in this proposed rule. It is hoped that this reflects a timing issue of the separate proposals and is not intended to delete the procedure of Suggested Restrictions Requirements (SRRs).

The Proposed Rule for Alternative Language in Claims Will Not Achieve the Stated Objectives

In all of the rule packages being advanced by the PTO, including this proposed rule the agency articulates the goal of reducing backlog. However, the practical result will be that more applications will be filed. BIO's members have for years experienced inconsistent and arbitrary restrictions. Based on existing practice, we believe that the application of the proposed restrictions within a claim will be similarly extensive. As an example, "unity of invention" considerations stem from an Examiner's position that elements differ in "structure" and focus on the structure similarity. However, the inventions in biotechnology often involve groups with a function not necessarily linked to the linear structure of the molecules. In such cases the species have a property in common which provides a common function thus meeting both the definition of Markush and unity of invention. In this situation Examiners often are not willing to consider such arguments and thus negate the biotechnology groupings of species. The PTO's new rules on continuations and claims will heighten this affect. Applicants will be willing to divide applications into several inventions. As a result, more applications will be filed to protect key features of the invention.

PTO Authority to Make the Proposed Changes is Questionable

The proposed rules interfere with an Applicant's ability to claim his or her invention as he believes it to be. Furthermore, the proposed rules appear to be in direct conflict with holdings by the Court of Customs and Patent Appeals (CCPA), the predecessor court of the Court of Appeals for the Federal Circuit (CAFC). As such, the statutory authority of the Director to promulgate the proposed rules under the auspice of 35 U.S.C. § 121 is in

substantial doubt.³ A brief examination of several well-established cases shows the limitations of § 121 to deal with single claims that may or may not contain patentably distinct subject matter.

The first of these cases, *In re Weber*, dealt with a rejection of a claim under § 121.⁴ In *Weber*, the CCPA addressed the ability of the PTO to reject claims in Markush form under § 121. The court held that § 121 was not a proper basis for rejection of a single claim, only as a basis for restriction of distinct inventions. The court explained that,

[a]s a general proposition, an applicant has a right to have each claim examined on the merits. If an applicant submits a number of claims, it may well be that pursuant to a proper restriction requirement, those claims will be dispersed to a number of applications. Such action would not affect the right of the applicant eventually to have each of the claims examined in the form he considers to best define his invention. If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on its merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the examiner rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification."⁵

Although this statement is dicta, the court's rationale is consistent with the language of the second paragraph of § 112 ("the specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention" (emphasis added)). Indeed, this language has been held to give the inventor the right to claim his invention as he contemplates it.⁶ BIO and its members recognize that the PTO must be allowed to exert some level of control over administrative matters with regard to Examiner workload. However the CCPA weighed the rights of the Applicant with the administrative needs of the PTO and concluded that "in drawing priorities between the Commissioner as administrator and the applicant as beneficiary of his statutory rights, we conclude that the statutory rights are paramount."⁷ The court then held that a rejection under § 121 violates an Applicant's statutory rights to claim the invention as the Applicant chooses.⁸

The *Weber* court held that § 121 "provides the Commissioner with the authority to promulgate rules designed to restrict an application to one of several claimed inventions when those inventions are found to be 'independent and distinct.'"⁹ "It does not,

³ It should also be noted that the proposed rules are arguably arbitrary, and therefore invalid, based solely on the language of the proposed rules. For example, the term "difficult to construe" is vague on its face.

⁴ *In re Weber*, 580 F.2d 455 (CCPA 1978).

⁵ *Id.* at 458.

⁶ *In re Wolfrum*, 486 F.2d 588 (CCPA 1973).

⁷ *Weber*, 580 F.2d at 459-60.

⁸ *Id.*

⁹ *Weber*, 580 F.2d at 458.

however, provide a basis for an examiner acting under the authority of the Commissioner to Reject a particular Claim on that same basis.”¹⁰ Judge Rich noted that the legislative history supports this interpretation, because, as enacted in the Patent Act of 1952, § 121 deals with divisional practice, not individual claims. He noted that, since the late 1800s, the phrase “two or more . . . inventions are claimed” in § 121 “has connoted separate claims to separate inventions It has no reference to generic or broad claims which ‘embrace’ . . . or ‘cover’ . . . two or more inventions.”¹¹

The ability of the PTO Director to promulgate rules consistent with § 121 is not questioned. However, this section has been held not to provide authority to reject an individual claim on this basis. Indeed, the CCPA held that a proposed rule that would allow for an Examiner to reject a single claim under § 121 had no basis in the statutory language.¹² If rejection of a claim that contains “independent and distinct” inventions is not proper under § 121, then a rule effectively preventing the filing of such a claim would also be outside the scope of § 121. This is especially true as the proposed rule impinges upon an Applicant’s rights to define and claim his or her invention under the language of § 112.

Furthermore, the proposed rules may interfere with an Applicant’s right to appeal a restriction requirement within a single claim issued by an Examiner. By allowing an Examiner to object to a claim that is “difficult to construe,” the proposed rules may undermine the right to appeal a restriction requirement or withdrawal of a genus claim that was established in another leading case *In re Haas*.

In considering the examiner’s action we look both to the language employed and the *effect* thereof. We consider the form and the substance. Although the principal opinion below considered the examiner’s language ‘most nearly suggestive of a restriction requirement,’ the effect of that language must also be considered. The particular packaging employed cannot be determinative.”¹³

Thus, under *Haas*, Applicants should be able to appeal an “objection” to a claim in improper form under the new rule, because the form and substance is no different than a restriction requirement. Despite the “particular packaging employed” by the proposed rules, an Applicant’s statutory right under § 112 to claim and define his invention will be impinged by an Examiner’s “objection.” An appropriate appeal should follow.

The court in *Haas* found that the withdrawal of the single claims said to include multiple independent and distinct inventions constituted a rejection.¹⁴ These claims were withdrawn from consideration not only in the pending application, but were prospectively

¹⁰ *Id.*

¹¹ *Weber*, 580 F.2d at 459 (Rich J. concurring).

¹² *See, In re Harnisch*, 631 F.2d 716, 721 (noting that, in *Haas*, the CCPA “held that § 121 could not be used as the basis for rejecting a single claim or compelling its replacement by a plurality of narrower claims before examination on the merits would be made”).

¹³ *In re Haas*, 486 F.2d 1053, 1055 (CCPA 1973)(emphasis in original).

¹⁴ *Id.*

withdrawn from subsequent applications because of their content. In effect, the Examiner's actions were a denial of patentability of the pending claims. As such, the *Haas* court, as described above, found that such an action was not supported under the auspices of § 121.

The proposed rules would allow an Examiner to take an all but identical approach to claim rejection under § 121. The absolute withdrawal under the new rules cannot properly be categorized as merely a "requirement" or "objection." An "objection" under the proposed rules is a denial of an Applicant's substantive rights. Thus, an "objection" to a claim using Markush language under the proposed rules is a rejection. Under *Haas*, review of an "objection" under the proposed rules must fall within the jurisdiction of the Board, and, ultimately, the CAFC.

The PTO relies heavily on *In re Harnisch*¹⁵ in arguing that procedural rules dealing with Markush claiming are allowable under the language of § 121.¹⁶ Reliance on *Harnisch* is misplaced for several reasons. First, it should be noted that the holding of *Harnisch* was that the contested Markush claims were proper.¹⁷ Additionally, to the extent the PTO is arguing otherwise, the *Harnisch* court adhered to the holdings of *Haas* and *Weber*, stating that "[n]othing we have said herein is intended to change or modify [*Haas* and *Weber*] in any way; nor do we think anything said could be reasonably construed to have such an effect."¹⁸ Thus, not only is *Harnisch* consistent with *Haas* and *Weber*, but also it cannot be read to overturn or contradict the holdings of the prior cases.

The *Harnisch* court recognized the possibility of a viable rejection based on an "improper Markush grouping."¹⁹ However, the decision also recognizes that there is no "specific statutory basis" for such a rejection.²⁰ Furthermore, the court cited deferentially to the holdings of *Haas* and *Weber* that an Applicant has the statutory right under § 112 to claim and define the invention. *Id.* Finally, the court recited several prior cases where rejections based on "improper Markush language" were overturned. Of particular note is that the court did not cite a single case in which such a rejection was upheld.²¹

The *Harnisch* court emphasized that, when faced with the issue of a single claim that may or may not contain patentably distinct inventions, the facts of the individual case must be taken into account.²² Indeed, the court cited several cases where factual analyses of compounds falling within disputed Markush claims resulted in reversal of initial rejections of those claims.²³ In essence, the court held that if a rejection based on "improper Markush language" is viable, such a rejection must be based on factual

¹⁵ 631 F.2d 716 (CCPA 1980).

¹⁶ See generally, 72 Fed. Reg. at 44992-45001.

¹⁷ *Harnisch*, 631 F.2d at 721.

¹⁸ *Id.* at 722 (emphasis added).

¹⁹ *Id.* at 721.

²⁰ *Id.*

²¹ The court did cite several cases noting that an Applicant must comply with the requirements of § 112.

²² *Harnisch*, 631 F.2d at 722.

²³ *Id.*

determinations.²⁴ However, the proposed rules deny such a factual analysis to Applicants. The proposed rules instead allow Examiners to reject claims based on nothing more than the language of the claims. For example, under proposed 37 C.F.R. § 1.175(j)(1), an Examiner may deny examination to a claim that is “difficult to construe.” Thus, the *Harnisch* decision does not support the proposed rules, and certainly does not support the removal of a factual analysis prior to depriving an Applicant of statutory rights without the ability to appeal.

Conclusion

BIO appreciates the challenges facing the PTO and recognizes that any improvements to the patent system to permit the PTO to review and issue patents more quickly and of higher quality are changes to be considered. However, because of the incalculable value of patents to all Applicants, any changes need to be carefully evaluated and limited to ensure a proper balancing of benefits and negative impacts. BIO believes that these proposed changes would adversely affect biotechnology Applicants, with potentially negative impacts on the American economy and society as a whole, and have not been justified in terms of potential benefits. Consequently BIO hopes the PTO will review the submitted comments and reconsider the proposed rule and abandon this significant change.

²⁴ *Id.* (analyzing prior case law and the pending case and concluding that “we decide this and like cases on their facts on a case-by-case basis” (emphasis added)).